



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 7, 2014

Zavation, LLC
Mr. John Walker
Engineering Manager
400 Liberty Park Drive
Flowood, Mississippi 39232

Re: K141005
Trade/Device Name: Zavation Z-Link Cervical
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: July 22, 2014
Received: July 24, 2014

Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141005

Device Name

Zavation Z-Link Cervical

Indications for Use (Describe)

The Z-Link Cervical is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Z-Link Cervical should be packed with autogenous bone graft and implanted with an anterior approach.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510K Summary

Date: August 4, 2014

Submitter: Zavation LLC
400 Liberty Park Drive
Flowood, MS 39232
Phone: 601-919-1119
Fax: 800-447-1302

Contact person: John Walker

Type of 510(k) submission: Traditional

Trade name: Zavation Z-Link Cervical

Common name: Intervertebral Body Fusion Device

Classification regulation: 21 CFR 888.3080 Intervertebral body fusion device

Device classification: Class II

Classification Panel: Orthopedic

Product code: OVE

Basis for submission: New device

Device Description:

The Zavation *Z-Link Cervical* includes a PEEK spacer, titanium interbody plate and screws. The spacer component is assembled to an interbody plate and implanted anteriorly. The endplate contacting surfaces of the spacer component include serrations, and the plate component includes two holes for inserting one bone screw in each vertebral body. The plate component also includes a screw lock at each hole. The bone screws are available in a variety of diameters and lengths. The interbody plate components are available in a variety of heights. The spacer components are available in a variety of depths, widths, and heights.

Intended Use:

The Z-Link Cervical is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Z-Link Cervical should be packed with autogenous bone graft and implanted with an anterior approach.

Materials:

The spacer component is manufactured from medical grade PEEK Zeniva ZA-500 (ASTM F2026) with a Tantalum alloy position marker (ASTM F560). The plate and screws are titanium alloy (ASTM F136).

Predicate Devices:

LDR Spine Cervical Interbody Fusion System (K091088)
Zavation IBF System (K120576)
Synthes Zero-P VA (K121852)
SpineSmith IN:C2 Spinal Fixation System (K122630)
Globus Coalition Spacer (K131449)

Performance Data:

Mechanical test results demonstrated that the Zavation Z-Link Cervical is substantially equivalent to the predicate devices. Testing was performed in accordance with:

- ASTM F2077, Test Methods for Intervertebral Body Fusion Devices
 - Static Axial Compression
 - Dynamic Axial Compression
 - Static Torsion
 - Dynamic Torsion
- ASTM F2267, Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression
- ASTM Draft F04.25.02.02, Static Pushout Test Method for Intervertebral Body Fusion Devices.